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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,884	10/23/2000	Kiyozo Asada	1422-443P	6983

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EXAMINER	
STRZELECKA, TERESA E	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 10/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/673,884	ASADA ET AL.	
	Examiner	Art Unit	
	Teresa E. Strzelecka	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16,18,31,34,36 and 38-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16,18,31,34,36 and 38-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/19/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This office action is in response to an amendment filed July 21, 2006. Claims 16, 18, 21-23, 31, 32, 34 and 36-38 were previously pending. Applicants cancelled claims 21-23, 32 and 37, amended claims 16 and 18 and added new claims 39-45. Claims 16, 18, 31, 34, 36 and 38-45 are pending and will be examined.

2. Applicants' amendments overcame the following rejections: rejection of claim 16 under 35 U.S.C. 102(b) as anticipated by Loeb et al.; rejection of claim 16 under 35 U.S.C. 102(b) as anticipated by Diringer et al.; rejection of claims 16, 31, 32 and 34 under 35 U.S.C. 102(b) as anticipated by Filler et al.; rejection of claims 18, 21, 23 and 36-38 under 35 U.S.C. 103(a) over Sorge et al. and Filler et al.; rejection of claims 18 and 22 under 35 U.S.C. 103(a) over Koster et al. and Filler et al.

3. This office action contains new grounds for rejection necessitated by amendment. However, this office action is made non-final because of newly presented double-patenting rejections.

Information Disclosure Statement

4. The information disclosure statement (IDS) submitted on June 19, 2006 was filed after the mailing date of the non-final office action on February 21, 2006. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 16, 18, 40-42 and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Miura et al. (EP 0 802 258 A2).

Regarding claims 16 and 18, Miura et al. teach a composition comprising a DNA polymerase, DNA which does not serve as template for DNA synthesis (the DNA is obtained by synthesis from nucleotides without the presence of a template or primers) and components necessary for DNA synthesis using a polymerase (page 3, lines 8-25; page 10, lines 30-37). Regarding claim 18, Miura et al. teach using two different DNA polymerases (page 16-21) and polymerases with 3'-5'exonuclease activity (e.g., Vent) and without the 3'-5' exonuclease activity (e.g. Taq polymerase) (page 8, lines 3-15).

Regarding claim 40, Miura et al. teach a 50 μL reaction mixture (page 11, lines 57-58), and they teach obtaining 9.5 mg of DNA product from a 475 mL reaction (page 12, lines 14-23). Therefore, the yield of DNA product was 0.02 μg/μL, so in a 50 μL reaction about 1 μg of the DNA would be produced, anticipating the limitation of 0.1 ng to about 5 μg.

Regarding claims 41, 42 and 45, Miura et al. teach *Thermococcus litoralis*-derived DNA polymerase, *Thermococcus acquaticus*-derived DNA polymerase, Vent DNA polymerase and Taq DNA polymerase (page 8, lines 3-15).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 31, 34, 36 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miura et al. (EP 0 802 258 A2) and Stratagene Catalog (page 39, 1988).

A) Miura et al. do not teach kits. Regarding claims 34 and 36, Miura et al. teach thermostable DNA polymerases (page 8, lines 3-15).

B) Stratagene catalog teaches a motivation to combine reagents into kit format (page 39).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine the compositions of Miura et al. into a kit format as discussed by Stratagene catalog since the Stratagene catalog teaches a motivation for combining reagents of use in an assay into a kit, "Each kit provides two services: 1) a variety of different reagents have been assembled and pre-mixed specifically for a defined set of experiments. Thus one need not purchase gram quantitites of 10 different reagents, each of which is needed in only microgram amounts, when beginning a series of experiments. When one considers all of the unused chemicals that typically accumulate in weighing rooms, desiccators, and freezers, one quickly realizes that it is actually far more expensive for a small number of users to prepare most buffer solutions from the basic reagents. Stratagene provides only the quantitites you will actually need, premixed and tested. In

actuality, the kit format saves money and resources for everyone by dramatically reducing waste. 2) The other service provided in a kit is quality control" (page 39, column 1).

10. Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Demeke et al. (Biotechniques, vol. 12, pp. 332, 334, 1992; cited in the IDS and in a previous office action) and Barnes (U.S. Patent No. 5,436,149 A; cited in a previous office action).

A) Demeke et al. teach DNA synthesis reaction compositions comprising Taq DNA polymerase and one of the following polysaccharides: carrageenan, pectin and dextran sulfate, together with reaction components necessary for DNA synthesis (Abstract; page 332, second paragraph; Table 1).

B) Demeke et al. do not teach a polymerase having 3'-5' exonuclease activity.

C) Barnes teaches a composition comprising two DNA polymerases, one with 3'-5' exonuclease activity and one without such activity (col. 3, lines 62-67; col. 4, lines 1-11; col. 16, lines 55-61).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to have used two polymerases with different 3'-5' exonuclease activities of Barnes in the composition of Demeke et al. The motivation to do so, provided by Barnes, would have been that using such polymerase combination allowed amplification of long DNA targets (col. 16, lines 55-61).

11. Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tasa et al. (Meth. Mol. Cel. Biol., vol. 5, pp. 122-124, 1995; cited in the IDS and in a previous office action) and Barnes (U.S. Patent No. 5,436,149 A; cited in a previous office action).

A) Tasa et al. teach a DNA synthesis reaction comprising a Taq DNA polymerase and heparin together with reaction components necessary for DNA synthesis (Abstract; page 123, second paragraph and paragraph entitled "Methodology").

B) Tasa et al. do not teach a composition comprising a DNA polymerase with 3'-5' exonuclease activity.

C) Barnes teaches a composition comprising two DNA polymerases, one with 3'-5' exonuclease activity and one without such activity (col. 3, lines 62-67; col. 4, lines 1-11; col. 16, lines 55-61).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to have used two polymerases with different 3'-5' exonuclease activities of Barnes in the composition of Tasa et al. The motivation to do so, provided by Barnes, would have been that using such polymerase combination allowed amplification of long DNA targets (col. 16, lines 55-61).

12. Claims 43 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Demeke et al. (Biotechniques, vol. 12, pp. 332, 334, 1992; cited in the IDS and in a previous office action) and Barnes (U.S. Patent No. 5,436,149 A; cited in a previous office action), as applied to claim 39 above, and further in view of Stratagene catalog (page 39, 1988; cited in a previous office action).

A) Demeke et al. and Barnes et al. teach the reaction composition of claim 39, but they do not teach kits.

B) Stratagene catalog teaches a motivation to combine reagents into kit format (page 39).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine the compositions of Demeke et al. and Barnes et al. into a kit format as discussed by Stratagene catalog since the Stratagene catalog teaches a motivation for combining reagents of use in an assay into a kit, "Each kit provides two services: 1) a variety of

different reagents have been assembled and pre-mixed specifically for a defined set of experiments. Thus one need not purchase gram quantitites of 10 different reagents, each of which is needed in only microgram amounts, when beginning a series of experiments. When one considers all of the unused chemicals that typically accumulate in weighing rooms, desiccators, and freezers, one quickly realizes that it is actually far more expensive for a small number of users to prepare most buffer solutions from the basic reagents. Stratagene provides only the quantitites you will actually need, premixed and tested. In actuality, the kit format saves money and resources for everyone by dramatically reducing waste. 2) The other service provided in a kit is quality control" (page 39, column 1).

13. Claims 43 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tasa et al. (Meth. Mol. Cel. Biol., vol. 5, pp. 122-124, 1995; cited in the IDS and in a previous office action) and Barnes (U.S. Patent No. 5,436,149 A; cited in a previous office action), as applied to claim 39 above, and further in view of Stratagene Catalog (page 39, 1988; cited in a previous office action).

A) Tasa et al. and Barnes et al. teach the composition of claim 39, but do not teach kits.

B) Stratagene catalog teaches a motivation to combine reagents into kit format (page 39).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine the compositions of Tasa et al. and Barnes et al. into a kit format as discussed by Stratagene catalog since the Stratagene catalog teaches a motivation for combining reagents of use in an assay into a kit, "Each kit provides two services: 1) a variety of different reagents have been assembled and pre-mixed specifically for a defined set of experiments. Thus one need not purchase gram quantitites of 10 different reagents, each of which is needed in only microgram amounts, when beginning a series of experiments. When one considers all of the unused chemicals that typically accumulate in weighing rooms, desiccators, and freezers, one quickly

realizes that it is actually far more expensive for a small number of users to prepare most buffer solutions from the basic reagents. Stratagene provides only the quantitites you will actually need, premixed and tested. In actuality, the kit format saves money and resources for everyone by dramatically reducing waste. 2) The other service provided in a kit is quality control" (page 39, column 1).

Double Patenting

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).
A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.
Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 16, 18 and 39 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 7 of U.S. Patent No. 6,673,578 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 7 of the '578 patent is a species of claims 16, 18 and 39.

Specifically, claim 7 of the '578 patent is drawn to a DNA synthesis method with a shortened time period for DNA synthesis by polymerase chain reaction (PCR), comprising the steps of: carrying out a DNA synthesis by PCR with a reaction mixture comprising: DNA polymerase, template DNA, dNTPs, and primers, wherein the amount of DNA polymerase added to said reaction mixture is pre-determined for each specific type of DNA polymerase by carrying out a test PCR reaction under the following conditions (A) and (B): (A) reaction mixture: 50 μL volume of a reaction mixture comprising DNA polymerase, 1 ng of genomic DNA from Escherichia coli, and 10 pmol each of primers Eco-1 (SEQ ID NO: 10) and Eco-2 (SEQ ID NO: 11); and having a composition suitable for said DNA polymerase; and (B) reaction conditions: 35 cycles of PCR, wherein one cycle consists of 99 C, 1 second-66 C, 7 seconds; wherein the amount of DNA polymerase used is that which is sufficient to provide more than 10 ng of amplified DNA fragments of about 2 kb per 50 μL of reaction mixture, wherein one DNA polymerase comprises 3'-5' exonuclease activity, and the other DNA polymerase comprises substantially no 3'-5' exonuclease activity, wherein said PCR is carried out in the presence of an acidic substance and/or a salt thereof, wherein said acidic substance is an acidic macromolecular substance, wherein said acidic macromolecular substance comprises a sugar chain backbone, wherein said acidic substance and/or salt thereof is one or more substances selected from the group consisting of sulfated-fucose-containing polysaccharides, dextran sulfate, carrageenan, heparin, rhamnam sulfate, chondroitin sulfate, dermatan sulfate, (chondroitin sulfate B), heparan sulfate, hyaluronic acid, alginic acid, pectin, polyglutamic acids, polyacrylic acids, polyvinyl sulfates, polystyrene sulfates, DNA and salts thereof.

Therefore, the method of claim 7 inherently uses A DNA synthesis reaction composition which anticipates the compositions of claims 16, 18 and 39.

16. Claims 16, 18, 31, 36, 39 and 43 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 10-17 of copending Application No. 10/435,633. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 10, 13, 14 and 17 of the 10/435,633 application anticipate claims 16 and 31 of the instant application, whereas claims 11, 12, 15 and 16 anticipate claims 18, 36, 39 and 43 of the instant application.

Specifically, claim 10 of the 10/435,633 application is drawn to a kit for carrying out a DNA synthesis method with a shortened time period for DNA synthesis by polymerase chain reaction (PCR), comprising:

(a) a DNA polymerase, of which amount per 1 reaction is 4 to 20 U as dNTPs-incorporating activity per 50 μL of a reaction mixture;

(b) at least one substance enhancing the DNA-synthesizing activity selected from the group consisting of sulfated-fucose-containing polysaccharides, dextran sulfate, carrageenan, heparin, rhamnam sulfate, chondroitin-sulfate, dermatan sulfate (chondroitin sulfate B), heparin sulfate, hyaluronic acid, alginic acid, pectin, polyglutamates, polyacrylates, polyvinyl sulfates, polystyrene sulfates, a 15-deoxyspergualin compound represented by the following general formula (I), degraded products of said 15-deoxyspergualin, and a salt thereof, wherein said degraded products of said 15-deoxyspergualin are any compounds represented by any of the general formulas (II), (III) and (IV), and

(c) a PCR reagent.

Claim 14 is drawn to a composition comprising:

(a) a DNA polymerase, of which amount per 1 reaction is 4 to 20 U as dNTPs-incorporating activity per 50 μL of a reaction mixture;

(b) at least one substance enhancing the DNA-synthesizing activity selected from the group consisting of sulfated-fucose-containing polysaccharides, dextran sulfate, carrageenan, heparin, rhamnam sulfate, chondroitin-sulfate, dermatan sulfate (chondroitin sulfate B), heparin sulfate, hyaluronic acid, alginic acid, pectin, polyglutamates, polyacrylates, polyvinyl sulfates, polystyrene sulfates, a 15-deoxyspergualin compound represented by the following general formula (I), degraded products of said 15-deoxyspergualin, and a salt thereof, wherein said degraded products of said 15-deoxyspergualin are any compounds represented by any of the general formulas (II), (III) and (IV), and

(c) a PCR reagent.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

17. No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E. Strzelecka whose telephone number is (571) 272-0789. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Teresa E Strzelecka
Primary Examiner
Art Unit 1637

Teresa Strzelecka

10/10/06